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EXAMINER

TUCKER, PHILIP C

ART UNIT	PAPER NUMBER
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1712

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042721

Applicant(s)

PILLAI ET AL.

Examiner

P. TUCKER

Group Art Unit

1712

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-4, 6, 11, 12, 39 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-4, 6, 11, 12, 39 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some* ☐ None of the:
 - ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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DETAILED ACTION

Election/Restriction

1. Applicants have elected to continue prosecution of the elected species which was selected in the parent application 08/471556, as confirmed with Donald Rhoads on 5/22/03. Applicant's elected species of 10-[2-[[3,5-bis[(2,3-dihydroxypropyl)amino]-carbonyl]phenyl]amino]-2-oxoethyl-1,4,7,10-tetraazacyclododecane-1,4,7-triacetic acid has been found to be allowable over the art of record. The species of substituted PA-DO3A in which R₁ and R₂ are lower alkyl or hydrogen, such that they combine to have at least 3 carbon atoms, has been examined in this action. Claims 1-4, 6 and 39 read upon this species.

Claim Objections

2. Claims 2, 3, 6, 11, 12 and 39 are objected to because of the following informalities: These claims teach that m' may be zero, which has the same meaning as A1 is a single bond, as previously cited in the claims. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 3, 6, 11, 12 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims teach that m may be zero, thus creating a direct single bond from the tetraaza-cyclododecane ring to the carbonyl group of the side chain. Such was not supported by the specification as originally filed and is new matter. Dependent claims fall herewith.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 11 teaches that the compound of the formula has the specific name of 10-[2-[[3,5-bis[(2,3-dihydroxypropyl)amino]-carbonyl]phenyl]amino]-2-oxoethyl-1,4,7,10-tetraazacyclododecane-1,4,7-triacetic acid, then teaches alternatives for each of the components of the formula, which are outside the scope of the specific compound. The scope of the claim is thus not clear. Dependent claim 12 falls herewith.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.


8. Claims 1-4, 6 and 39 are rejected under 35 U.S.C. § 103 as being unpatentable over Society of Magnetic Resonance in Medicine, Book of Abstracts, 8th Annual Meeting, August 12-18, 1989.

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Society of Magnetic Resonance teaches the biodistribution of Gd complex PA-DO3A in mice as a function of lipophilicity. Society of Magnetic Resonance differs from the selected species of the present invention in that an alkyl group (propyl or butyl), or 2 alkyl groups comprising at least 3 carbon atoms (methyl + ethyl), are replaced by hydrogen atoms. As homologues with such similar structures would be expected to have similar properties and utility, it would be obvious to one of ordinary skill in the art to make various homologues of PA-DO3A, including the methyl compound of the present invention, for use in the study of lipophilicity in mice. There is clear basis in case law for rejections of obviousness based upon homology in which an alkyl group, or more than one alkyl group is substituted for hydrogen in a known molecule (Ex parte Faque 121 USPQ 425). See also In re Wood 199 USPQ 137 and In re Hoch 166 USPQ 406, cited by the Board of Appeals in parent application 08/471556.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip Tucker whose telephone number is (703) 308-0529. The examiner's normal working hours are 7:30am-4:00pm, Monday-Friday. If necessary SPE Robert Dawson may be contacted at 703-308-2340. For inquiries of a general nature call the receptionist at 703-308-0651. The group FAX no. is 703-872-9310. The **after final** fax no. Is 703-872-9311.

PCT-2814
May 27, 2003


PHILIP C. TUCKER
ART UNIT 1712